CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S27

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA No. 5-970

Date 25 March 1985

ESI Pharmaceuticals
Elkins-Sinn, Inc.
P. O. Box 5483
Cherry Hill, NJ 08034

Attn: Ms. Thelma C. Hillbrand

Gentlemen:

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Sotradecol Injection

NDA Number: 5-970

Supplement Number: S-027 (Resubmission)
S-028 (Practitioner Draft Labeling)

Date of Supplement: February 13, 1985

Date of Receipt: February 19, 1985

All communications concerning this NDA should be addressed as follows:

Center for Drugs and Biologics, HFN-160
Attention: Document Control Room 18B-03
5600 Fishers Lane
Rockville, MD 20857

Sincerely Yours,

Supervisory Consumer Safety Officer
Division of Surgical-Dental Drug Products
Center for Drugs and Biologics

FORM FDA 3217f (4/84)

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NDA SUPPL FOR Resubmission

ELKINS-SINN, INC. 2 Esterbrook Lane, Post Office Box 5483 Cherry Hill, N.J. 08034
A Subsidiary of A. H. Robins Company
N.J. 609 424-3700
Phila. 215 925-4559

NDA NO. 5-970 REF. NO. 5-028 PD

NDA SUPPL FOR Labeling

February 13, 1985

Patricia H. Russell, M.D.
Acting Director
Division Surgical-Dental Drug Products
HFN-160 Rm. #18B-08
Center for Drugs & Biologics
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NDA 5-970/S-027
Sotradecol^{R} Injection

Response to Deficiency Letter of 6/18/84 - S-027

Dear Dr. Russell:

This letter is sent in response to the letter noted above regarding Sotradecol Gel. We are enclosing the additional information requested:

1. Acceptable release specifications and tests for residual solvents. As listed on the enclosed SAT (Specifications and Testing) for the Gel, we are allowing not more than % petroleum ether and not more than % acetone.

   All the referenced tests for the Gel, i.e. T.P. 131, 133, 134, 135 and 269 are included in their entirety.

2. Specification and test for pyrogenicity in the final product. We are enclosing the SATs for the final products, Sotradecol Injections 1% and 3%. The specification (conforms to USP XXI) and test (Bacterial Endotoxin) for pyrogenicity are listed thereon.

Draft Labeling

1. We are submitting draft labeling, as requested which follows the format of 21 CFR 201.57.

2. The Description section of the insert has been revised to include Sotradecol's chemical name, structural formula and therapeutic class.

3. We have added a Storage section to the How Supplied section, as requested.

4. Labels and Insert Description to list pyrogenicity. We have added the word nonpyrogenic to the Description. However, we have not added it to the immediate label and box for reasons that go beyond space limitations. We believe it is understood that an intravenous injection is nonpyrogenic just as it is understood to be sterile, unless labeled otherwise. Injections are not required to have "Sterile" on the labels. Therefore, why should they be required to have nonpyrogenic on the label? Such labeling should be done only if the product is pyrogenic or non-sterile. It is our opinion that if FDA is to require nonpyrogenic on injectable products, a clear policy should be established which would apply to all products in the class rather than having individual drugs arbitrarily selected.

The specification and test method for the pyrogenicity is listed on the final product SAT sheets (see item #2). For the data you requested, we are including the Summaries of the LAL Validation tests for Sotradecol 1% and 3% solutions. Except for the data on the Gel which belongs in Section 8d, the remaining enclosed data is intended to supplement Section 8n.

Please do not hesitate to call if questions arise upon reading this response.

Sincerely,

ELKINS-SINN, INC.

Thelma C. Hilibrand

Thelma C. Hilibrand
Manager, Regulatory Affairs

TCH/mh
Enclosures